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## Comparison of Magnetic Resonance Imaging and Serum Biomarkers for Detection of Human Pluripotent Stem Cell-Derived Teratomas.

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### Public Summary:

The use of cells derived from pluripotent stem cells (PSCs) for regenerative therapies confers a considerable risk for neoplastic growth and teratoma formation. Preclinical and clinical assessment of such therapies will require suitable monitoring strategies to understand and mitigate these risks. Here we generated human-induced pluripotent stem cells (iPSCs), selected clones that continued to express reprogramming factors after differentiation into cardiomyocytes, and transplanted these cardiomyocytes into immunocompromised rat hearts post-myocardial infarction. We compared magnetic resonance imaging (MRI), cardiac ultrasound, and serum biomarkers for their ability to delineate teratoma formation and growth. MRI enabled the detection of teratomas with a volume >8 mm<sup>3</sup>. A combination of three plasma biomarkers (CEA, AFP, and HCG) was able to detect teratomas with a volume >17 mm<sup>3</sup> and with a sensitivity of more than 87%. Based on our findings, a combination of serum biomarkers with MRI screening may offer the highest sensitivity for teratoma detection and tracking.

### Scientific Abstract:

The use of cells derived from pluripotent stem cells (PSCs) for regenerative therapies confers a considerable risk for neoplastic growth and teratoma formation. Preclinical and clinical assessment of such therapies will require suitable monitoring strategies to understand and mitigate these risks. Here we generated human-induced pluripotent stem cells (iPSCs), selected clones that continued to express reprogramming factors after differentiation into cardiomyocytes, and transplanted these cardiomyocytes into immunocompromised rat hearts post-myocardial infarction. We compared magnetic resonance imaging (MRI), cardiac ultrasound, and serum biomarkers for their ability to delineate teratoma formation and growth. MRI enabled the detection of teratomas with a volume >8 mm<sup>3</sup>. A combination of three plasma biomarkers (CEA, AFP, and HCG) was able to detect teratomas with a volume >17 mm<sup>3</sup> and with a sensitivity of more than 87%. Based on our findings, a combination of serum biomarkers with MRI screening may offer the highest sensitivity for teratoma detection and tracking.

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